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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,613	01/24/2002	Fred Christians	3386.1	9358

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AFFYMETRIX, INC  
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.  
3380 CENTRAL EXPRESSWAY  
SANTA CLARA, CA 95051

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
1637	10

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/683,613

Applicant(s)

CHRISTIANS ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/24/02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Applicant's preliminary amendment filed in Paper No. 3 is acknowledged and has been entered. Claims 1-21 are pending in the instant application. Applicant's transmittal of substitute drawings is acknowledged and has been entered.

#### ***Priority***

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

#### ***Drawings***

3. The drawings are objected to because the drawings are difficult to read, perhaps due to copy machine artifacts in that the shading and small size makes interpretation difficult. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the abandonment of the application.

#### ***Claim Objections***

4. Claims 7-11 are objected to under 37 CFR 1.75(c) as being in improper form because the claims depend from the multiple dependent claim 6 and a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, for the purposes of application of prior art, the claims 7-11 are being interpreted as depending from claim 2.

***Claim Rejections - 35 USC § 112: Indefiniteness***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 2 lacks proper antecedent basis for the recitation of "oligonucleotide tags" because claim 1 from which it depends does not recite an "oligonucleotide tag" but recites a "nucleic acid tag". It is suggested amending the claims such that the claim language agrees.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 9-15 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Baskerville et al (WO 99/54458, October 28, 1999). Baskerville et al teach method for screening polypeptides comprising linking each of the polypeptides to nucleic acid tags to obtain tagged polypeptides; hybridizing the tagged polypeptide to a solid surface comprising probe (binding partner) sequences complementary to each of the nucleic acid tags linked to the polypeptides and screening the polypeptides for biological activity/function. Baskerville et al additionally teach that the solid surface may comprise of beads, chips or other planar surfaces, wells or columns. Baskerville et al teach that because there is no limit on the number of different possible nucleic acid tags, an essentially unlimited number of different (uniquely or specifically) tagged polypeptides can be produced and once produced, the tagged polypeptides can be analyzed via

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hybridization to DNA arrays (page. 23 line 21 to col. 24, line 15 and page. 26, line 4 to page 27, line 7; see also page 25, lines 16- 30 and Figure 3).

9. Regarding claim 3, 4, 14 and 15, Baskerville et al teach wherein the screening comprises determining the binding affinity of the immobilized polypeptides with a ligand wherein said ligand is a drug candidate (page 26, line 14 to page 27, line 7).

10. Regarding claims 9-11 and 20-21, Baskerville et al teach that an unlimited number of polypeptides may be tagged with a specific (different) nucleic acid (pages 26, lines 4-6). Therefore, Baskerville et al. anticipates the claims 1-5, 9-15 and 19-21 of the instant invention.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claims 6-11 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baskerville et al. as previously applied above in view of Fodor et al (US 5,871,928, February 16, 1999). Regarding claim 6-8 and 16-18, Baskerville et al teach a method for screening a plurality of polypeptides comprising linking each of the plurality of polypeptides with a nucleic acid tag to obtain tagged polypeptides. The reference further teaches wherein hybridization to a chip array may occur for polypeptide screening processes wherein the chip array comprises oligonucleotides complementary to the unique and distinct tags. The method of Baskerville et al differs from the instant invention in that the reference does not teach wherein the chip array comprises at least 400 or 1000 or 10000 different oligonucleotide probes per  $\text{cm}^2$ . Fodor et al teaches a method analyzing polynucleotide or a polypeptide sequence via hybridization to an oligonucleotide array. Fodor et al describe the array as a composition comprising a plurality of positionally distinguishable sequence specific reagents attached to a solid substrate, which reagents are capable of specifically binding to a predetermined subunit sequence of a preselected multi-subunit length (col. 2, lines 54-60). The reference teaches wherein the subunit may be a polynucleotide or a polypeptide (col. 2, lines 61-62). Fodor et al additionally teach wherein the oligonucleotide array may comprise from at least 50 oligonucleotides to an excess of one million oligonucleotides (col. 20, lines 5-23). Fodor et al teach that the method for analyzing polypeptides or polynucleotides using oligonucleotide probe arrays is useful because it provides a improved means for de novo sequencing of an unknown polymer sequence, for verification of know sequences and for mapping homologous segments with a sequence by reducing the number of manual manipulations required and automation of most of the steps. Fodor states that thus the speed, accuracy and reliability of these procedures are greatly enhanced (col. 2, lines 21-28).

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Therefore, in view of the foregoing one of ordinary skill in the art would have been motivated at the time of the claimed invention to have provided a an oligonucleotide array comprising at least 400 to 10000 oligonucleotides for the polypeptide screening method as taught by Baskerville. One of ordinary skill in the art would have been motivated to do so for the advantages taught by Fodor et al. that by analyzing polypeptides or polynucleotides using oligonucleotide probe arrays are useful because one provides a means of reducing the number of manual manipulations required and automation of most of the steps, therefore greatly enhancing the speed, accuracy and reliability of the these procedures (col. 2, lines 21-28).

### ***Conclusion***

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

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Cynthia B. Wilder, Ph.D.

Examiner

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cbw

October 9, 2003

A handwritten signature in cursive script that reads "Cynthia B. Wilder". The signature is fluid and stylized, with the first and last names being more prominent than the middle initial.

**CYNTHIA WILDER**  
**PATENT EXAMINER**